

REMARKS

First, Applicant's counsel would like to thank Examiner Yabut for discussing the rejection of claims 1-12 and 31-42 in a telephone interview conducted August 1, 2007. Specifically, the combination of Gambale (U.S. Pub. No. 2003/0208209) and McAlister (U.S. Patent No. 6,398,795) as used to reject the pending claims under 35 U.S.C. § 103(a) was discussed during the interview. Applicant's counsel first argued that McAlister does not disclose a removable septum, and Examiner Yabut agreed that the stapler 50 in McAlister is not removable. Examiner Yabut also agreed with counsel that there is no motivation or suggestion in Gambale to remove the septum of the device for the reasons discussed below. Based on the below arguments, Examiner Yabut stated that preliminarily the claims were in condition for allowance.

Claims 1-12 and 31-42 are currently pending, and have been rejected in the outstanding office action. Reconsideration is requested.

Claims 1-12 and 31-42 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gambale (U.S. Pub. No. 20030208209) in view of McAlister et al. (US Pat. No. 6,398,795). Applicant respectfully traverses the rejection for the reasons discussed below.

Examiner states that Gambale does not disclose a septum being removable from between the first and second openings, as recited in claim 1, or first and second ports, as recited in claim 31, and that Gambale does not disclose the septum being adapted for abrading adjacent tissue. Further, Examiner states that "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to provide a removable septum, as taught by McAlister, to Gambale in order to facilitate appositioning of the tissues after they are separated by the first and second

openings or ports as well as to provide selective separation of the first and second areas of tissue." Applicant respectfully disagrees with the rejection as not all of the claim limitations are taught or suggested by the cited reference because neither Gambale nor McAlister disclose a removable septum. Applicant also disagrees with the rejection because there is no motivation to combine a removable septum with the device of Gambale, since the combination would destroy the intended purpose of Gambale.

First, McAlister does not disclose first and second openings being separated by a septum. Instead, the device in McAlister has only one window 20 for adhering to one area of tissue as shown in FIG. 3C, or window 20" in FIG. 5A. Reference numeral 50" refers to the stapling device, not a septum. See col. 4, lines 38-42 of McAlister et al. In McAlister, the stapling device 50 moves from a retracted position shown in FIG. 3A to a stapling position shown in FIG. 3B, and McAlister et al. does not disclose that the stapling device is removable. Also, instead of the stapling device 50 or 50" being "removable from between the first and second openings to allow the at least one fastener to be deployed such that the first area of tissue is secured to the second area of via the fastener," as recited in independent claim 1 of the current application, the stapling device 50" closes or moves to a stapling position (FIG. 3B) to fire staples into the acquired tissue. Similarly, independent claim 31 recites "a septum positioned between the first port and the second port, wherein the septum is removed to allow the first area of tissue to be secured to the second area of tissue via the fastener." For these reasons, McAlister does not teach a removable septum as recited in claims 1 or 31, and since all of the claim limitations are not taught or suggested by the cited references, claims 1-12 and 31-42 are patentable over Gambale in view of McAlister.

The 35 U.S.C. § 103(a) rejection of the pending claims should also be withdrawn, since the combination of references is improper and the device of Gambale would not work for the intended purpose if it were combined with a removable septum. With reference to FIGS. 40 and 41 and paragraph [0171], the Gambale device operates by drawing two tissue portions 890 into two separate vacuum chambers 860. The vacuum chambers are formed within the device such that a portion of the external surface 852 divides the two chambers. To place a suture through the two folds of tissue, a needle 880 passes through a channel 894 and through the double folds of tissue acquired by the device. See paragraphs [0171] and [0172] of Gambale. Therefore, the exterior surface 852, which the Examiner refers to as a septum, does not need to be removable to allow a fastener to be deployed to secure the first area of tissue to the second area of tissue, because there is a channel 894 that provides a passage way for the needle 880 to pass through to secure the dual folds of tissue.

Gambale contains no teaching, suggestion, or motivation to replace or modify the suturing method using the needle 880 passing through channel 894 as shown in FIG. 40, with stapler 50" of McAlister. The only possible motivation for combining McAlister with Gambale came from applicant's own disclosure, which is impermissible use of hindsight. Therefore, there is no motivation or suggestion found in either Gambale or McAlister to combine a stapler with the Gambale device.

In fact, removing the septum 852 would defeat the intended purpose of Gambale, which is to "secure multiple tissue portions 52 simultaneously for application of a tissue securing device, such as a suture, tag or staple." See paragraph [099] of Gambale. As discussed in Gambale, the advantage of the Gambale device over the prior art is that it secures "two tissue portions 52 in the same number of steps that the prior art device requires to secure a single tissue

portion." Id. If the septum 852 is removed while the tissue is acquired, the acquisition of two folds of tissue would be lost and only one fold would remain to be secured. Therefore, the Gambale device combined with a removable septum would eliminate the intended purpose of Gambale, to acquire and secure multiple folds of tissue together simultaneously. This is an impermissible combination of references under M.P.E.P. § 2143.01. In other words, Gambale teaches away from having a removable septum as recited in independent claims 1 and 31, because the device in Gambale requires a stationary septum 852 to separate the vacuum chambers 860 and create two folds of tissue to be secured together. Accordingly, claims 1-12 and 31-42 are patentable over Gambale in view of McAlister.

In view of the foregoing, Applicant respectfully submits that all pending claims are now in condition for allowance. Reexamination and reconsideration of the application are respectfully requested and allowance at an early date is solicited.

The Commissioner is authorized to charge deposit account no. 06-2425 for any unforeseen fees arising from the filing of this paper.

Respectfully submitted,
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